

**Union Calendar No. 255**

106TH CONGRESS  
1ST SESSION

**H. R. 2634**

**[Report No. 106–441, Part I]**

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**A BILL**

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment.

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NOVEMBER 3, 1999

Reported from the Committee on Commerce with an amendment

NOVEMBER 3, 1999

Referral to the Committee on the Judiciary extended for a period ending not later than November 3, 1999

NOVEMBER 3, 1999

Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 1999

Mr. BLILEY (for himself, Mr. GREEN of Texas, Mr. OXLEY, Mr. BOUCHER, Mr. COX, Mr. GREENWOOD, and Mr. COBLE) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

NOVEMBER 3, 1999

Reported from the Committee on Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

NOVEMBER 3, 1999

Referral to the Committee on the Judiciary extended for a period ending not later than November 3, 1999

NOVEMBER 3, 1999

Additional sponsors: Mr. NORWOOD, Mr. DEAL of Georgia, Mr. RANGEL, and Mr. UPTON

NOVEMBER 3, 1999

Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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# A BILL

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       *This Act may be cited as the “Drug Addiction Treat-*  
5       *ment Act of 1999”.*

6       **SEC. 2. AMENDMENT TO CONTROLLED SUBSTANCES ACT.**

7       *(a) IN GENERAL.—Section 303(g) of the Controlled*  
8       *Substances Act (21 U.S.C. 823(g)) is amended—*

9               *(1) in paragraph (2), by striking “(A) security”*  
10              *and inserting “(i) security”, and by striking “(B) the*  
11              *maintenance” and inserting “(ii) the maintenance”;*

12              *(2) by redesignating paragraphs (1) through (3)*  
13              *as subparagraphs (A) through (C), respectively;*

14              *(3) by inserting “(1)” after “(g)”;*

15              *(4) by striking “Practitioners who dispense” and*  
16              *inserting “Except as provided in paragraph (2),*  
17              *practitioners who dispense”; and*

1           (5) by adding at the end the following para-  
2       graph:

3       “(2)(A) Subject to subparagraphs (D) and (I), the re-  
4       quirements of paragraph (1) are waived in the case of the  
5       dispensing (including the prescribing), by a practitioner,  
6       of narcotic drugs in schedule IV or V or combinations of  
7       such drugs if the practitioner meets the conditions specified  
8       in subparagraph (B) and the narcotic drugs or combina-  
9       tions of such drugs meet the conditions specified in subpara-  
10      graph (C).

11       “(B) For purposes of subparagraph (A), the conditions  
12      specified in this subparagraph with respect to a practi-  
13      tioner are that, before dispensing narcotic drugs in schedule  
14      IV or V or combinations of such drugs to patients for main-  
15      tenance or detoxification treatment, the practitioner submit  
16      to the Secretary a notification of the intent of the practi-  
17      tioner to begin dispensing the drugs or combinations for  
18      such purpose, and that the notification contain the fol-  
19      lowing certifications by the practitioner:

20           “(i) The practitioner is a qualifying physician  
21       (as defined in subparagraph (G)).

22           “(ii) With respect to patients to whom the prac-  
23      titioner will provide such drugs or combinations of  
24      drugs, the practitioner has the capacity to refer the

1       *patients for appropriate counseling and other appro-*  
2       *priate ancillary services.*

3               “(iii) *In any case in which the practitioner is*  
4       *not in a group practice, the total number of such pa-*  
5       *tients of the practitioner at any one time will not ex-*  
6       *ceed the applicable number. For purposes of this*  
7       *clause, the applicable number is 40, except that the*  
8       *Secretary may by regulation change such total num-*  
9       *ber.*

10              “(iv) *In any case in which the practitioner is in*  
11       *a group practice, the total number of such patients of*  
12       *the group practice at any one time will not exceed*  
13       *the applicable number. For purposes of this clause,*  
14       *the applicable number is 40, except that the Secretary*  
15       *may by regulation change such total number, and the*  
16       *Secretary for such purposes may by regulation estab-*  
17       *lish different categories on the basis of the number*  
18       *of practitioners in a group practice and establish for*  
19       *the various categories different numerical limitations*  
20       *on the number of such patients that the group prac-*  
21       *tice may have.*

22              “(C) *For purposes of subparagraph (A), the conditions*  
23       *specified in this subparagraph with respect to narcotic*  
24       *drugs in schedule IV or V or combinations of such drugs*  
25       *are as follows:*

1           “(i) The drugs or combinations of drugs have,  
2           under the Federal Food, Drug, and Cosmetic Act or  
3           section 351 of the Public Health Service Act, been ap-  
4           proved for use in maintenance or detoxification treat-  
5           ment.

6           “(ii) The drugs or combinations of drugs have  
7           not been the subject of an adverse determination. For  
8           purposes of this clause, an adverse determination is  
9           a determination published in the Federal Register  
10          and made by the Secretary, after consultation with  
11          the Attorney General, that the use of the drugs or  
12          combinations of drugs for maintenance or detoxifica-  
13          tion treatment requires additional standards respect-  
14          ing the qualifications of practitioners to provide such  
15          treatment, or requires standards respecting the quan-  
16          tities of the drugs that may be provided for unsuper-  
17          vised use.

18          “(D)(i) A waiver under subparagraph (A) with respect  
19          to a practitioner is not in effect unless (in addition to con-  
20          ditions under subparagraphs (B) and (C)) the following  
21          conditions are met:

22                 “(I) The notification under subparagraph (B) is  
23                 in writing and states the name of the practitioner.

24                 “(II) The notification identifies the registration  
25                 issued for the practitioner pursuant to subsection (f).

1           “(III) If the practitioner is a member of a group  
2           practice, the notification states the names of the other  
3           practitioners in the practice and identifies the reg-  
4           istrations issued for the other practitioners pursuant  
5           to subsection (f).

6           “(ii) The Secretary shall assign a unique identifier to  
7           each notification under subparagraph (B), and shall pro-  
8           vide to the Attorney General all information contained in  
9           such notifications.

10          “(E)(i) If a practitioner is not registered under para-  
11          graph (1) and, in violation of the conditions specified in  
12          subparagraphs (B) through (D), dispenses narcotic drugs  
13          in schedule IV or V or combinations of such drugs for main-  
14          tenance treatment or detoxification treatment, the Attorney  
15          General may, for purposes of section 304(a)(4), consider the  
16          practitioner to have committed an act that renders the reg-  
17          istration of the practitioner pursuant to subsection (f) to  
18          be inconsistent with the public interest.

19          “(ii)(I) A practitioner who in good faith submits a no-  
20          tification under subparagraph (B) and reasonably believes  
21          that the conditions specified in subparagraphs (B) through  
22          (D) have been met shall, in dispensing narcotic drugs in  
23          schedule IV or V or combinations of such drugs for mainte-  
24          nance treatment or detoxification treatment, be considered

1 to have a waiver under subparagraph (A) until notified oth-  
2 erwise by the Secretary.

3 “(II) For purposes of subclause (I), the publication in  
4 the Federal Register of an adverse determination by the Sec-  
5 retary pursuant to subparagraph (C)(ii) shall (with respect  
6 to the narcotic drug or combination involved) be considered  
7 to be a notification provided by the Secretary to practi-  
8 tioners, effective upon the expiration of the 30-day period  
9 beginning on the date on which the adverse determination  
10 is so published.

11 “(F)(i) With respect to the dispensing of narcotic drugs  
12 in schedule IV or V or combinations of such drugs to pa-  
13 tients for maintenance or detoxification treatment, a prac-  
14 titioner may, in his or her discretion, dispense such drugs  
15 or combinations for such treatment under a registration  
16 under paragraph (1) or a waiver under subparagraph (A)  
17 (subject to meeting the applicable conditions).

18 “(ii) This paragraph may not be construed as having  
19 any legal effect on the conditions for obtaining a registra-  
20 tion under paragraph (1), including with respect to the  
21 number of patients who may be served under such a reg-  
22 istration.

23 “(G) For purposes of this paragraph:



1           “(i) The term ‘group practice’ has the meaning  
2           given such term in section 1877(h)(4) of the Social  
3           Security Act.

4           “(ii) The term ‘qualifying physician’ means a  
5           physician who is licensed under State law and who  
6           meets one or more of the following conditions:

7                   “(I) The physician holds a subspecialty  
8                   board certification in addiction psychiatry from  
9                   the American Board of Medical Specialties.

10                   “(II) The physician holds an addiction cer-  
11                   tification from the American Society of Addic-  
12                   tion Medicine.

13                   “(III) The physician holds a subspecialty  
14                   board certification in addiction medicine from  
15                   the American Osteopathic Association.

16                   “(IV) The physician has, with respect to the  
17                   treatment and management of opiate-dependent  
18                   patients, completed not less than eight hours of  
19                   training (through classroom situations, seminars  
20                   at professional society meetings, electronic com-  
21                   munications, or otherwise) that is provided by  
22                   the American Society of Addiction Medicine, the  
23                   American Academy of Addiction Psychiatry, the  
24                   American Medical Association, the American Os-  
25                   teopathic Association, the American Psychiatric

1        *Association, or any other organization that the*  
2        *Secretary determines is appropriate for purposes*  
3        *of this subclause.*

4                *“(V) The physician has participated as an*  
5        *investigator in one or more clinical trials lead-*  
6        *ing to the approval of a narcotic drug in sched-*  
7        *ule IV or V for maintenance or detoxification*  
8        *treatment, as demonstrated by a statement sub-*  
9        *mitted to the Secretary by the sponsor of such*  
10       *approved drug.*

11               *“(VI) The physician has such other training*  
12       *or experience as the State medical licensing*  
13       *board (of the State in which the physician will*  
14       *provide maintenance or detoxification treatment)*  
15       *considers to demonstrate the ability of the physi-*  
16       *cian to treat and manage opiate-dependent pa-*  
17       *tients.*

18               *“(VII) The physician has such other train-*  
19       *ing or experience as the Secretary considers to*  
20       *demonstrate the ability of the physician to treat*  
21       *and manage opiate-dependent patients. Any cri-*  
22       *teria of the Secretary under this subclause shall*  
23       *be established by regulation. Any such criteria*  
24       *are effective only for three years after the date on*  
25       *which the criteria are promulgated, but may be*

1       *extended for such additional discrete 3-year peri-*  
2       *ods as the Secretary considers appropriate for*  
3       *purposes of this subclause. Such an extension of*  
4       *criteria may only be effectuated through a state-*  
5       *ment published in the Federal Register by the*  
6       *Secretary during the 30-day period preceding the*  
7       *end of the 3-year period involved.*

8       “(H) *During the 3-year period beginning on the date*  
9       *of the enactment of the Drug Addiction Treatment Act of*  
10      *1999, any law or regulation of a State or political subdivi-*  
11      *sion of a State that is in conflict with this paragraph is*  
12      *superseded by this paragraph. If before the expiration of*  
13      *such period a State or political subdivision of a State en-*  
14      *acts such a law, then upon the expiration of the period this*  
15      *paragraph ceases to supersede the law.*

16      “(I)(i) *This paragraph takes effect on the date of the*  
17      *enactment of the Drug Addiction Treatment Act of 1999,*  
18      *and remains in effect thereafter except as provided in clause*  
19      *(iii) (relating to a decision by the Secretary or the Attorney*  
20      *General that this paragraph should not remain in effect).*

21      “(ii) *For purposes relating to clause (iii), the Sec-*  
22      *retary and the Attorney General may, during the 3-year*  
23      *period beginning on the date of the enactment of the Drug*  
24      *Addiction Treatment Act of 1999, make determinations in*  
25      *accordance with the following:*

1           “(I) The Secretary may make a determination of  
2       whether treatments provided under waivers under  
3       subparagraph (A) have been effective forms of mainte-  
4       nance treatment and detoxification treatment in clin-  
5       ical settings; may make a determination of whether  
6       such waivers have significantly increased (relative to  
7       the beginning of such period) the availability of  
8       maintenance treatment and detoxification treatment;  
9       and may make a determination of whether such waiv-  
10      ers have adverse consequences for the public health.

11           “(II) The Attorney General may make a deter-  
12      mination of the extent to which there have been viola-  
13      tions of the numerical limitations established under  
14      subparagraph (B) for the number of individuals to  
15      whom a practitioner may provide treatment; may  
16      make a determination of whether waivers under sub-  
17      paragraph (A) have increased (relative to the begin-  
18      ning of such period) the extent to which narcotic  
19      drugs in schedule IV or V or combinations of such  
20      drugs are being dispensed or possessed in violation of  
21      this Act; and may make a determination of whether  
22      such waivers have adverse consequences for the public  
23      health.

24           “(iii) If, before the expiration of the period specified  
25      in clause (ii), the Secretary or the Attorney General pub-

lishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.”.

(b) CONFORMING AMENDMENTS.—Section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) in subsection (a), in the matter after and below paragraph (5), by striking “section 303(g)” each place such term appears and inserting “section 303(g)(1)”; and

(2) in subsection (d), by striking “section 303(g)” and inserting “section 303(g)(1)”.

1 **SEC. 3. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS**  
2 **REGARDING DEPARTMENT OF HEALTH AND**  
3 **HUMAN SERVICES.**

4 *For the purpose of assisting the Secretary of Health*  
5 *and Human Services with the additional duties established*  
6 *for the Secretary pursuant to the amendments made by sec-*  
7 *tion 2, there are authorized to be appropriated, in addition*  
8 *to other authorizations of appropriations that are available*  
9 *for such purpose, such sums as may be necessary for fiscal*  
10 *year 2000 and each subsequent fiscal year.*